HIA

HEARING INDUSTRIES ASSOCIATION

515 King Street
Suite 420
Alexandria, VA
22314

Phone: 703-684-5744
Fax: 703-684-6048

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Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99N-0035, Medical Devices; Reclassification of 38 Preamendments Class III Devices Into Class II

Dear Sir/Madam:

We are submitting comments in the above referenced matter in support of FDA's proposal to reclassify from class III to class II the tinnitus masker which presently is classified under 21 CFR § 874.3400. This class III device is identified as follows:

A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.
21 CFR § 874,3400(a)

Essentially, the device blocks or masks unwanted internally originating sounds to provide comfort to users and to assist in the hearing of external noises. The device is straightforward and not subject to significant regulatory concerns such as significant changes in technology or off label use.

FDA's proposal to reclassify the device has substantial merit. First, enough is known about the device to place it in class II with special controls. Tinnitus maskers have over a 30 year history of use and represent a mature technology with no change in basic functionality. Indeed, the only design change associated with the type of device is miniaturization. The device has a strong safety and effectiveness record with no reported MDRs or reported safety and effective problems associated with proper use. Additionally, tinnitus maskers are made of well-established biocompatible materials, all of which are commonly and widely used in hearing aids.

99N-0035

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Second, tinnitus maskers, even if volume controls are abused by users, cannot produce sound pressure levels which are capable of damaging residual hearing. This type of device typically produces sound pressure levels that range from 40 to 70 SPL. These levels are unaffected by ambient sound pressure levels and are controlled by the patient. When adjusted for the patient, the sound pressure level is set to the patient's preference and comfort. Simply put, the sound pressure output for tinnitus maskers cannot present a risk to health because device volume is totally within a patient's control and not influenced by external sources.

Third, tinnitus maskers are fitted to patients like hearing aids, a class I device. Further, the battery of tests used in the fitting process is similar to those used in fitting hearing aids. The only expected adjustment of a tinnitus masker is the volume control which, as stated above, a patient can set. In other words, the device does not present any challenge to fitting a patient.

Last, given the device's relative simplicity, its mature technology, the absence of off label use, and safety and effectiveness record, the agency now knows enough to rely on class II controls to ensure safety and effectiveness. Specifically, the law is clear that preamendment devices may be reclassified from class III to class II if "the [FDA] determines that special controls would provide reasonable assurance of the safety and effectiveness of the device. . . ." § 513(e)(2). FDA proposes a labeling special control to ensure safety and effectiveness of tinnitus maskers to provide such an assurance and HIA concurs.

In the proposed reclassification, the agency states that "(1) Patient labeling to include information about: (i) Risks, (ii) Benefits, (iii) Warnings for safe use, and (iv) Technical specifications, and (2) Medical consultation for: (i) Determination of the cause of tinnitus, (ii) Fitting of the device, and (iii) Follow-up care by a hearing health care professional." 64 *Fed. Reg.* 12792. Although we believe that the tinnitus masker's device risk is minimal and its normal use is safe, HIA concurs with the agency's judgment to provide complete consumer information, including technical specifications, in an understandable format for consumers. Additionally, HIA concurs that a consultation to determine the cause of tinnitus and appropriate follow-up care should be part of a special control to assure safety and effectiveness.

In conclusion, we support the FDA's reclassification proposal for tinnitus maskers. The agency's interest in avoiding costly and unnecessary PMAs for devices like the tinnitus masker through reclassification furthers the public interest by making useful, lower risk devices available to consumers more expeditiously and preserving FDA's finite premarket review resources for newer, complex devices that truly require product-by-product safety and effectiveness reviews.

Sincerely,

Carole M. Rogin
President